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13. ABSTRACT (Maximum 200 Words)

The study aims to determine racial differences between insulin-like growth factor-1 (IGF-1), insulin-like binding protein-1 (IGFBP-2), insulin-like binding protein-3 (IGFBP-3), prostate specific antigen (PSA), testosterone, body mass index (BMI), and diets high in calories, protein and fat. Specifically, the primary objectives are to:

* define racial differences in serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, and testosterone.
* define how diet and BMI impact serum levels of IGF-1, IGFBP-2, IGFBP-3, testosterone, PSA in African American and Caucasian men.
* determine the association between serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, testosterone, PSA, BMI, and specific nutrients.

The proposed study will help to explain the increased risk of prostate cancer for African American men and the role of specific nutrients n influencing IGF-1 and IGF-binding protein concentrations. This report covers primarily patient accrual activities during the first and second year of the project. These activities include finalizing the clinical protocol, hiring and training of study personnel, reviewing clinical questionnaires to determine study eligibility, and determination of stored frozen samples for use. A total of 544 men were recruited to participate in the study. Approximately 1,294 assays have been analyzed for IGF-1, IGF-binding proteins and testosterone. A total of 300 men were stratified and randomized for the telephone interview. Of this number, 138 men agreed to be interviewed and completed the nutrition questionnaires.

14. SUBJECT TERMS
IGF-insulin growth factor type 1; IGFBP-2-insulin growth factor binding protein 2; IGFFBP-3-insulin growth factor binding protein 3; PSA-prostate-specific androgen;

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INTRODUCTION

Presently, prostate cancer is the most common cancer in U.S. males. In 1999, the American Cancer Society estimates that 179,300 new cases will be diagnosed and approximately 37,000 men will die from metastatic prostate cancer (1). The incidence and mortality rates are even greater in African-American men than among other racial or ethnic populations in the world. Prostate cancer incidence rates are nearly two times higher for African-American men than for white men (2). The incidence and mortality rate for prostate cancer in the Washington, D.C. area is the highest in the world. Moreover, the rate of increase in prostate cancer occurs earlier for black males than white males (3). Evidence suggest that African Americans may be at higher risk since they consume diets higher in energy and fat and have made smaller changes in decreasing fat intake when compared to Caucasian men (4).

Insulin-like growth factor-1 (IGF-1) and IGF-binding proteins have been implicated in the carcinogenesis of breast, prostate and other hormone dependent cancers. Insulin-like growth factor-1 functions in an autocrine and paracrine manner to promote normal growth and malignant cellular proliferation (5-7). IGF-1 is produced by normal prostate cells (8) prostate cancer cells (9) and has mitogenic and antiapoptotic effects (10,11) on prostate epithelial cells (12). Several epidemiological studies have shown increased plasma levels of IGF-1 to be a strong risk factor for prostate cancer (13-15). Chan et al. (14) examined plasma levels of IGF-1 and IGFBP-3 in a prospective case-control study and found mean levels of IGF-1 to be significantly elevated among the prostate cases when compared to the controls. The relative risk was 4.3 (95% CI= 1.8-10.6) for men in the highest quartile of IGF-1 levels when compared with men in the lowest quartile. Higher plasma IGF-1 concentrations were associated with higher rates of malignancy in the prostate gland. Also, plasma levels of IGFBP-3 were inversely associated with risk after controlling for IGF-1 levels.

Another study (15) found a statistically significant positive association between serum levels of IGF-1 and risk of prostate cancer (OR=1.51; 95% CI=1.0-2.26 per 100 ng/ml increment). In this study serum levels of IGFBP-3 were not significantly associated with prostate cancer risk. However, Kanety et al. (16) found that patients with metastatic prostate cancer had significant reductions in both the absolute and relative amounts of IGFBP-3 and significantly higher serum IGFBP-2 concentrations when compared with the controls. The authors suggested that IGFBP's might be involved in growth modulation of prostate malignancy.

Several researchers have reported elevated serum IGFBP-2 concentrations (16-18) in patients with prostate cancer. It was suggested that elevations in serum IGFBP-2 concentrations might be unique to the carcinomatous condition (17). Ho et al. (18) suggested that IGFBP-2 might function as an IGF scavenger when the capacity of IGFBP-3 to bind IGF-1 in the serum is insufficient in patients with prostate cancer. Taken together, these studies strongly support a relationship between IGF-1, specific

IGF-binding proteins and prostate cancer risk. To date, no published studies have examined racial difference in IGF-1 levels or systematically examined these associations in a healthy high risk screening population.

Prostate Specific Antigen (PSA), produced by the prostate epithelium, is elevated in patients with prostate cancer. Thus, PSA is considered a sensitive marker to monitor and detect disease. Studies show that PSA correlates with IGF-binding proteins. Ho et al. (18) found a positive correlation between serum levels of IGFBP-2 and PSA levels in patients with prostate cancer. The study results suggest that serum IGFBP-2 levels, like PSA, may reflect the tumor load in prostate cancer. Kanety et al. (16) also found that serum IGFBP-2 levels and its percentage of the total IGFBPs were highly positively correlated with serum PSA. In that study, a negative correlation was also found between IGFBP-3 and PSA. (16). These studies are consistent with findings in another study that showed IGFBP-2 elevated to a similar mean level when serum PSA was greater than 150 ug/l (17). It was suggested that the proteolysis effect of PSA on IGFBP potentiates the growth-promoting effects of IGF-1 on prostate cells. The researchers believe that PSA might serve to modulate IGF function within the reproductive system or in prostate cancer by altering IGF-IGFBP-3 interaction (17).

Researchers have examined various androgens as possible risk factors for prostate cancer. Ross et al (19) demonstrated that young African-American men had serum testosterone levels that were approximately 15% higher than their white counterparts. Research conducted by Erfurth et al. (20) showed that in a group of healthy men serum levels of IGF-1 increased with increasing free testosterone ($p=0.005$). In this study IGFBP-1 was significantly and positively correlated with free-testosterone and total testosterone.

Environmental factors, such as obesity and diet, have been shown to influence prostate cancer risk. Obesity has been shown to be associated with endocrine changes and is believed to be a risk factor for prostate cancer. Although the relationship between prostate cancer and obesity is somewhat inconsistent, two retrospective studies (21,22) and several prospective studies (23-26) have reported associations with body mass index (BMI) and prostate cancer risk. Andersson et al. (26) conducted a prospective study of 135,000 male construction workers who were followed for an average of 18 years. This study revealed a positive association of weight, height, BMI and lean body mass with risk of prostate cancer. Moreover, these anthropometric measures were more strongly associated with mortality. Obesity is also believed to be associated with IGF-1 levels. In a study of healthy males, free IGF-1 concentrations were higher in obese subjects than in normal controls (27). IGFBP-2 concentrations were also suppressed in the obese subjects. The researchers suggested that overnutrition and chronic hyperinsulinamia in obesity might alter the regulated growth response by insulin stimulation of IGF-1 production and suppression of hepatic IGFBP-1 and IGFBP-2 production, which may inhibit IGF-1 bioactivity.

Nutrition is a key regulator of IGF's and IGF-binding proteins (28) and prostate cancer risk. Specifically, energy restriction is associated with lower concentrations of IGF-1 (28,29) and a reduction in tumor growth, thus favoring cell apoptosis over cell proliferation (15). Isley et al. (30) showed diets deficient in protein and energy intake decreased IGF-1 levels. In this study, changes in serum IGF-1 concentrations correlated significantly with mean daily nitrogen balance. Also, serum levels of IGFBP-2 and

IGFBP-3 are inversely regulated by dietary protein and caloric intake as well as fasting (28). Investigators (31-33) have shown significant positive associations between total energy intake, dietary fat intake and prostrate cancer risk. These associations were more pronounced for cases with aggressive cancers (31,33). Andersson et al. (33) hypothesized that a high-energy, high fat, high-protein diet might influence prostate cancer risk mediated by IGF-1 concentrations. However, the relationships between IGF-1 and specific nutrients are not well understood, and those factors and the mechanisms of action requires further study.

Diet and obesity may play a significant role in understanding the relationships between serum IGF-1, IGFBP-2 and IGFBP-3 concentrations and prostate cancer risk. We believe serum levels of IGF-1, IGFBP-2 and IGFBP-3 may influence the etiology of prostate cancer and can serve as markers for this disease. Also, a low-fat, high-fiber diet has been shown to decrease circulating testosterone levels by altering male sex hormone metabolism (34,35). The proposed study can increase our understanding of the role of diet and obesity in modulating serum IGF-1 and IGF-binding proteins. Thus, reducing body weight/body fat may prevent or reduce prostate cancer risk. Understanding the associations between IGF-1, specific IGF-binding proteins, testosterone, PSA, BMI and diet in a healthy, screening population may help to better understand the etiology of this disease.

Hypotheses/Purpose

The purpose of this study is to examine racial differences in prostate cancer risk in a healthy high risk screening population of African American and Caucasian males. The associations between IGF-1, IGF-binding proteins (2&3), PSA, testosterone, and BMI will be examined. The study aims to determine racial differences between IGF-1, IGFBP-2, IGFBP-3, PSA, testosterone, BMI, and diets high in calories, protein and fat. Specifically, the study objectives are to:

- define racial differences in serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, and testosterone
- define how diet and BMI impact serum levels of IGF-1, IGFBP-2, IGFBP-3, testosterone and PSA in African American and Caucasian men.
- determine the associations between serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, testosterone, PSA, BMI and specific nutrients.

The proposed study will help to explain the increased risk of prostate cancer for African American men and the role of specific nutrients in influencing IGF-1 and IGF-binding protein concentrations.

This report covers primarily patient accrual activities during the first year of the project. These activities include finalizing the clinical protocol, hiring and training of study personnel, reviewing clinical questionnaires to determine study eligibility, and determination of stored frozen samples for use.

BODY

Study progress through year three will be described below with respect to each of the tasks in the Statement of Work.

Statement of Work

Task 1: **Hiring and Training of Staff**

The grant was officially awarded December 1999, but did not start until April 2000 due to concerns expressed by the Human Subjects Protection, AMDEX Corporation. In March, a medical research assistant was employed to work on the project. Study protocol was finalized and a training session was held to discuss study goals, objectives, protocols, responsibilities and data collection procedures.

Task 2: **Obtain and review clinical questionnaires of 1,517 men who participated in prostate screenings to identify men eligible for the study**

The clinical questionnaires were obtained from the men who participated in prostate screenings at the Lombardi Cancer Center, Georgetown University. The questionnaires were categorized by race, age, and cancer status. Computer entries of all questionnaires were inputted in Microsoft Excel.

Task 3: **Obtain PSA values for men who are eligible for the study.**

PSA results were obtained for all men and computer entry of results was inputted in Microsoft Excel.

Task 4: **Work with Director of Serum Bank to retrieve serum for men eligible for the study.**

We worked closely with Dr. Bruce Trock, who was the Director of the Serum Bank, Georgetown University to retrieve serum collected from prostate screenings that were stored at the Serum Bank. Dr. Trock informed us that some of the stored samples were frozen in the wrong tubes, stored as whole blood or were not centrifuged. Therefore, we conducted preliminary studies to determine the reliability and validity of IGF-1, IGFBP-2, and IGFBP-3 in whole blood when compared to serum. Samples were obtained from 10 volunteers participating in Dr. Trocks project. Dr. Kevin Cullen, who is an investigator with this project, had his laboratory to conduct the comparative analysis. Results from the analysis revealed that the samples were not appropriate for our study. Therefore, we recruited new men who came to prostate screenings at the Lombardi Cancer Center and the Howard University Cancer Center. A total of 544 men were recruited for this project.

Task 5: **Analyze serum for IGF-1, IGFBP-2, IGFBP-3 and testosterone.**
Serum analysis is currently being conducted in Dr. Kevin Cullen's laboratory at the Lombardi Cancer Center. To date, approximately 1,294 assays are completed. This includes 311 assays analyzed for IGF-1, 504 assays analyzed for IGFBP-2, 268 assays analyzed for IGFBP-3 and 211 assays were analyzed for testosterone. *See appendices for assay methodology, assays completed and standard curves.*

Task 6: **Stratify and randomize over 300 men for telephone interview.**
We have stratified 300 men who are eligible for the telephone interview.

Task 7: **Send letters to 300 men requesting telephone interview.**
Letters were sent to 300 men who were stratified requesting an interview.

Task 8: **Call 300 men to schedule telephone interview.**
A total of 300 men were called to schedule a telephone interview.

Task 9: **Conduct telephone interview.**
A total of 138 men, which consisted of 83 African Americans and 55 Caucasians agreed to complete the short nutrition questionnaire over the phone. There were many reasons for the low participation of men scheduled to be interviewed. Some reasons included non working telephone numbers and no answer. However, many of the men we were able to contact, were not interested or stated they were too busy to participate.

Task 10: **Mail monetary incentive to interviewees.**
Monetary incentives were mailed to all men who completed the nutrition questionnaire over the telephone.

Task 11: **Data entry and analyze; complete final report.**
Data entry has been completed for 138 nutrition questionnaires and 1,294 serum assays consisting of IGF-1, IGFBP-2, IGFBP-3 and testosterone. Serum analysis and data entry are on-going. Final report will be completed when data analysis is finalized.

KEY RESEARCH ACCOMPLISHMENTS

- Hiring and training of personnel working on project.
- Finalization of study protocol.
- Obtained and reviewed clinical questionnaires of 1,517 men who had stored serum
- Preliminary analysis to determine if stored blood was appropriated for our study.
- Obtained PSA values for men who had stored blood.
- Data entry of clinical information from questionnaires and PSA values.
- Recruited 544 men who participated in recent prostate screening.
- Completed 1,294 IGF-1, IGFBP-2, IGFBP-3 and testosterone assays.
- Stratified, randomized and called 300 men for the telephone interview.
- Conducted telephone interview with 138 study participants.
- Data entry of 138 nutrition questionnaires from telephone interviews.
- Data entry of 1,294 of IGF-1, IGFBP-2, IGFBP-3 and testosterone assays.

REPORTABLE OUTCOMES

None at this time.

CONCLUSIONS

Study personnel was hired and trained. The clinical protocol was finalized. Approximately 1500 clinical questionnaires were reviewed to determine study eligibility. Data entry of clinical information and PSA's were completed for all eligible subjects. However, there were unanticipated obstacles in sorting out which frozen blood samples were appropriate for analysis of study variables. Preliminary analysis was conducted to compare the validity ad reliability of IGF-1, IGFBP-2, and IGFBP-3 in whole blood versus serum. It was determined that the frozen blood samples (whole blood was not appropriate for use in this study.

Since the frozen samples of whole blood could not be used for this project, we began recruiting men who attended prostate screening at the Lombardi Cancer Center and the Howard University Cancer Center. To date, we have recruited 544 men. From these men, approximately 1,294 assays have been analyzed for IGF-1, IGFBP-2, IGFBP-3 and testosterone. A total of 300 men were stratified and randomized for the telephone

interview. Letters requesting a telephone interview were sent to 300 men. Of this number138 were interviewed to determine nutrition intake.

In March 2003, we requested a no-cost one-year extension for this project to allow additional time to complete serum analysis, data entry, data analysis and final report. Our request was approved on March 21, 2003. We are confident that the study objectives will be completed within the one-year extension.

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APPENDICES

LIST OF ABBREVIATIONS AND ACRONYMS

IGF	insulin growth factor type 1
IGFBP-2	insulin growth factor binding protein 2
IGFBP-3	insulin growth factor binding protein 3
PSA	prostate-specific androgen

Meeting abstracts during reporting period: None in connection with this project

Publications during reporting period: None in connection with this project

Manuscripts in preparation: None in connection with this project

Personnel receiving pay from this negotiated effort:

Dr. Kevin Cullen

SERUM ASSAY METHODOLOGY

IGFBP-2 Assay

IGFBP2 Radioimmunoassay (RIA) (Diagnostics Systems Laboratories (DSL), Webster, Texas; kit DSL-7100): Serum samples were assayed in duplicate according to the manufacturer's instructions. The RIA procedure measures competition between a radioactive and non-radioactive antigen for a fixed number of antigen binding sites. The amount of I125-labeled IGFBP-2 bound to the antibody is inversely proportional to the concentration of unlabeled IGFBP-2 present. Separation of the free and bound antigen is achieved by using a double antibody system. Briefly, serum specimens were pre-incubated with anti-IGFBP2 polyclonal antibody, incubated further (overnight) after the addition of I125-labeled IGFBP-2, and antigen-bound antibody was precipitated using polyclonal anti-rabbit gamma globulin serum in a buffer containing polyethylene glycol. Sample radioactivity was measured in a gamma counter (Packard Cobra II Auto-Gamma). Results were determined from a semilog standard curve plotting %B/Bzero [mean sample counts – nonspecific background counts (NSB)] / [mean counts of 0 ng/ml standard – NSB] versus the log of standard IGFBP-2 concentrations, as recommended by the manufacturer.

Two supplied controls were included on each assay plate, Level I (low, 5.5 +/- 1.6) and Level II (high, 18 +/- 5.4). On one occasion (12/14/01 assay), the Level II assayed value (24. 8) was slightly outside the confidence interval determined by the manufacturer (12.6 - 23.4). The Level I value was within range (6.1). The modest departure of the Level II value from the confidence interval was not considered sufficient to exclude the assay results. For all other assays, control values fell within range.

Serum samples were diluted 1:30, 1:40 or 1:50. The first assay (11/21/01) was performed using the manufacturer's typical recommended dilution of 1:50. Based on those results, where 11 of 40 samples fell below the lowest standard, the dilution was adjusted to 1:40 for the second assay (12/1/01). Since 10 of 40 samples fell below the lowest standard at that dilution, the dilution was adjusted to 1:30 for the third assay (12/7/01), and all but one sample fell within range of the standard curve. Subsequent assays were performed using a dilution of 1:30. Samples for which a serum IGFBP-2 value could not determine because the diluted sample was below the lowest standard will be retested at a lower dilution. All other values within the range of the standard curve were valid and are reported.

Serum IGF1 Assay

Non-extraction IGF-1 Enzyme-Linked Immunosorbent Assay (ELISA) (DSL, kit DSL-10-2800): Serum samples were assayed in duplicate according to the manufacturer's instructions. The ELISA procedure is an enzymatically amplified sandwich immunoassay. Absorbance measurement from a colorimetric reaction is directly proportional to the concentration of IGF-1 present. Briefly, following overnight

pretreatment in sample buffer, samples were incubated in microplate wells coated with an anti-IGF1 antibody. Wells were washed, and enzyme-conjugated anti-IGF1 antibody added for a second incubation. Following washing, the substrate tetramethylbenzidine was added. The reaction was stopped after ten minutes with an acidic stopping solution, and the absorbance at 450 nm determined using a microplate reader (Molecular Devices THERMOmax). Sample IGF1 values were determined from a standard curve plotting the log of mean absorbance versus the log of standard IGF-1 concentrations, as recommended by the manufacturer.

Two supplied controls were included on each assay plate. For all assays, assayed values for the controls were within the manufacturer's confidence intervals.

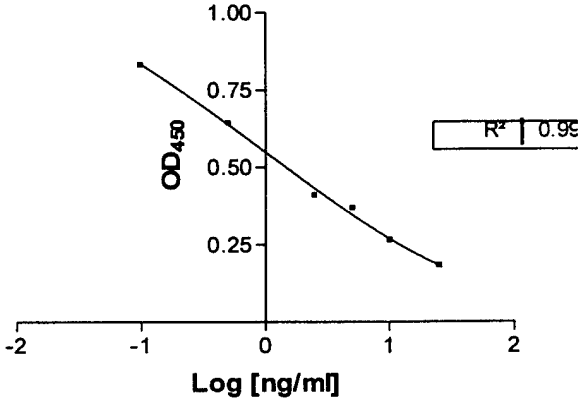
Serum IGFBP-3 Assay

IGFBP-3 ELISA (DSL, kit DSL-10-6600): Serum samples were assayed in duplicate according to the manufacturer's instructions. Briefly, diluted serum samples were incubated in microplate wells coated with an anti-IGFBP-3 polyclonal antibody. Wells were washed, and enzyme-conjugated anti-IGFBP-3 polyclonal antibody added for a second incubation. Following washing, the substrate tetramethylbenzidine was added. The reaction was stopped after ten minutes with an acidic stopping solution, and the absorbance at 450 nm determined using a microplate reader. Sample IGFBP-3 values were determined from a standard curve plotting the log of mean absorbance versus the log of standard IGFBP-3 concentrations, as recommended by the manufacturer.
Two supplied controls were included on each assay plate. For each assay, assayed values for the controls were within the confidence interval determined by the manufacturer.

Sample	Patient	ng/ml	SD	intra.
19	6	5.91	0.62	11%
9	17	4.32	0.36	8%
11	19	5.10	0.22	4%
3	20	2.32	0.07	3%
35	21	7.21	0.64	9%
34	22	4.16	0.07	2%
27	25	3.86	0.43	11%
23	26	5.15	0.41	8%
30	39	9.81	0.72	7%
4	40	3.37	0.27	8%
8	48	5.86	0.25	4%
17	442	5.37	0.23	4%
36	453	5.26	0.64	12%
7	454	16.96	1.50	9%
26	527	7.54	0.48	6%
32	542	3.71	0.46	12%
5	545	8.49	0.22	3%
2	589	5.86	0.54	9%
18	625	9.45	0.56	6%
21	627	5.78	0.78	14%
24	655	4.20	0.52	12%
16	741	6.62	1.29	20%
33	743	7.37	0.70	10%
12	752	5.76	0.60	10%
25	753	7.31	0.60	8%
29	760	9.10	0.66	7%
28	773	8.00	0.57	7%
6	774	3.65	0.36	10%
10	775	4.29	0.41	10%
1	778	3.40	0.00	0%
22	779	4.47	0.27	6%
31	780	8.97	0.59	7%
14	785	5.10	0.09	2%
20	787	8.07	0.16	2%
13	797	8.04	0.52	6%
15	818	3.24	0.11	3%
	Level I	0.54	0.08	15%
	Level II	7.44	0.33	4%

Number of values	36
Minimum	2.318
25% Percentile	4.243
Median	5.769
75% Percentile	7.771
Maximum	16.96
Mean	6.196
Std. Deviation	2.717
Std. Error	0.4529
Lower 95% CI	5.277
Upper 95% CI	7.116

Testosterone EIA1/27/03



(0.3 - 0.7)

(3 - 7)

Interassay samples

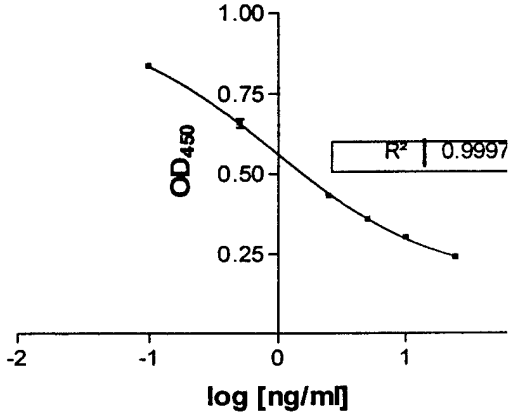
	12/20 #4	LMS	KN
########	5.63 +/- .55	.68 +/- .09	
1/10/2003	4.19 +/- .45	.61 +/- .09	
1/27/2003	6.12 +/- .65	.99 +/- .38	14.47 +/- .52
Mean	5.31	0.76	
SD	1.00	0.20	
Interassay	19%	27%	

Current assay

Sample	Patient	ng/ml	SD	Intraassay
19	1	3.41	0.36	10%
9	2	4.85	0.40	8%
25	5	5.15	0.07	1%
24	8	6.65	0.15	2%
23	9	6.23	0.52	8%
20	11	3.77	0.24	6%
31	12	3.03	0.04	1%
5	18	2.48	0.07	3%
32	24	2.90	0.26	9%
33	46	3.30	0.32	10%
7	49	2.67	0.02	1%
27	443	3.47	0.41	12%
22	445	2.46	0.27	11%
36	446	3.36	0.25	7%
30	447	6.50	0.15	2%
2	449	1.61	0.02	1%
34	450	11.76	1.06	9%
3	457	3.74	0.05	1%
12	501	3.10	0.20	7%
15	503	2.90	0.50	17%
14	526	3.82	0.02	1%
21	539	4.62	0.25	5%
10	547	2.54	0.13	5%
13	564	7.23	0.70	10%
17	566	4.41	1.07	24%
11	577	3.38	0.10	3%
26	652	5.25	0.45	9%
8	737	4.33	0.11	3%
29	742	4.41	0.24	5%
6	777	4.02	0.05	1%
1	778	3.06	0.00	0%
35	784	2.32	0.26	11%
4	796	3.91	0.05	1%
18	798	2.57	0.03	1%
28	799	2.71	0.05	2%
16	801	1.06	0.03	3%
	Level I	0.27	0.01	4%
	Level II	4.74	0.36	8%

Number of values	36
Minimum	1.055
25% Percentile	2.806
Median	3.437
75% Percentile	4.515
Maximum	11.76
Mean	3.971
Std. Deviation	1.926
Std. Error	0.321
Lower 95% CI	3.32
Upper 95% CI	4.623

Testosterone EIA 1/29/03



(0.3 - 0.7)
(3 - 7)

Interassay samples

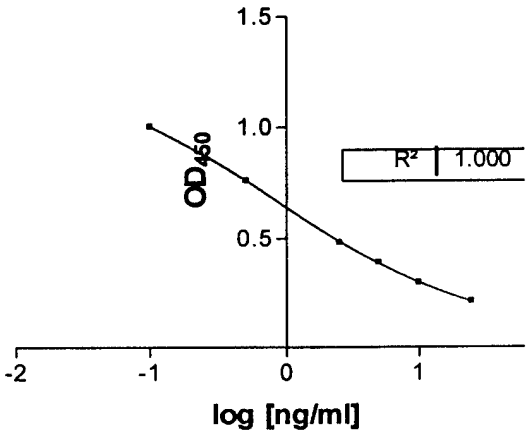
	12/20 #4	LMS	KN	778
12/10/2002	5.6 +/- .55	0.68 +/- .09		
1/10/2003	4.2 +/- .45	0.61 +/- .09		
1/27/2003	6.1 +/- .65	0.99 +/- .38	14.5 +/- .52	3.4
1/29/2003	5.1 +/- .25	0.37 +/- .04	10.7 +/- .71	3.06 +/- .00
Mean	5.25	0.66	12.57	3.23
SD	0.83	0.26	2.69	0.24
Interassay	15.8%	39.0%	21.4%	7.4%

Current assay

Sample	Patient	ng/ml	SD	Intraassay
25	45	2.95	0.03	1%
6	53	2.58	0.05	2%
34	57	6.34	0.45	7%
1	93	3.78	0.07	2%
24	96	4.80	0.00	0%
22	109	3.72	0.23	6%
4	111	7.43	0.30	4%
27	481	7.97	0.09	1%
21	483	7.80	0.05	1%
23	493	6.13	0.00	0%
31	498	10.64	1.16	11%
5	507	5.06	0.24	5%
7	546	4.34	0.04	1%
18	546	4.36	0.37	8%
3	571	9.40	0.06	1%
17	571	9.64	0.06	1%
2	575	7.08	0.28	4%
11	575	7.46	0.26	3%
26	578	4.61	0.16	4%
33	595	5.14	0.51	10%
12	606	6.20	0.03	1%
10	622	3.31	0.33	10%
8	635	4.13	0.00	0%
19	635	5.90	0.32	5%
13	639	15.32	0.33	2%
36	641	4.10	0.16	4%
16	649	1.89	0.03	2%
20	653	6.78	1.76	26%
14	666	6.29	0.38	6%
15	676	9.40	0.63	7%
32	680	3.98	0.10	2%
30	694	4.33	0.15	3%
9	703	4.81	0.02	1%
28	717	6.47	0.00	0%
29	771	8.07	0.43	5%
35	x	5.83	0.66	11%
	Level I	0.76	0.04	5%
	Level II	4.37	0.22	5%

Number of values	36
Minimum	1.892
25% Percentile	4.229
Median	5.865
75% Percentile	7.446
Maximum	15.32
Mean	6.056
Std. Deviation	2.637
Std. Error	0.4395
Lower 95% CI	5.164
Upper 95% CI	6.949

Testosterone EIA 1/31/03



(0.3 - 0.7)
(3 - 7)

Interassay samples

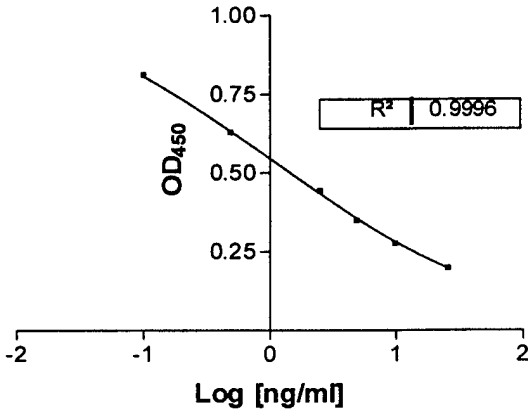
	12/20 #4	LMS	KN	778
12/10/2002	5.6 +/- .55	0.68 +/- .09		
1/10/2003	4.2 +/- .45	0.61 +/- .09		
1/27/2003	6.1 +/- .65	0.99 +/- .38	14.5 +/- .52	3.4
1/29/2003	5.1 +/- .25	0.37 +/- .04	10.7 +/- .71	3.06 +/- .00
1/31/2003	5.4 +/- .34	0.75 +/- .05	15.4 +/- 3.8	
Mean	5.27	0.68	13.51	3.23
SD	0.72	0.23	2.50	0.24
Interassay	13.7%	33.8%	18.5%	7.4%

Current assay

Sample	Patient	ng/ml	SD	Intraassay
2	58	5.68	0.37	6%
35	67	4.78	0.60	13%
6	76	4.91	0.25	5%
17	104	3.54	0.19	5%
32	456	5.00	0.00	0%
18	499	4.64	0.55	12%
9	506	2.81	0.02	1%
13	509	12.09	0.71	6%
11	514	7.02	0.37	5%
34	516	2.53	0.06	2%
15	531	3.15	0.11	4%
28	549	1.90	2.69	141%
20	567	3.02	0.62	20%
7	572	5.21	0.03	1%
26	573	3.61	0.04	1%
10	574	3.69	0.48	13%
27	580	2.62	0.09	4%
23	594	4.17	0.60	14%
36	598	7.26	0.24	3%
25	600	10.11	0.36	4%
3	613	3.68	0.04	1%
21	631	4.40	0.63	14%
24	643	4.19	0.26	6%
22	647	6.86	0.96	14%
14	663	6.70	0.09	1%
29	665	7.54	0.15	2%
12	673	4.85	0.52	11%
8	675	4.08	0.51	12%
31	702	2.43	0.06	2%
19	704	8.26	0.79	10%
30	724	3.99	0.72	18%
1	730	4.40	0.03	1%
16	739	9.38	0.39	4%
4	749	6.64	0.26	4%
33	755	3.64	0.00	0%
5	786	15.10	0.93	6%
	Level I	0.59	0.02	4%
	Level II	6.17	1.13	18%

Number of values	36
Minimum	1.901
25% Percentile	3.629
Median	4.516
75% Percentile	6.782
Maximum	15.1
Mean	5.386
Std. Deviation	2.837
Std. Error	0.4729
Lower 95% CI	4.425
Upper 95% CI	6.346

Testosterone EIA 2/3/03



(0.3 - 0.7)
(3 - 7)

Interassay samples

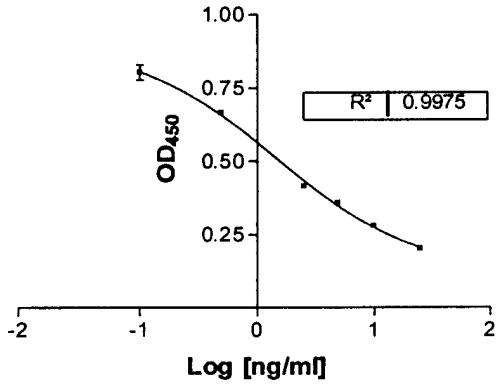
	12/20 #4	LMS	KN	778
#######	5.6 +/- .55	0.68 +/- .09		
#######	4.2 +/- .45	0.61 +/- .09		
#######	6.1 +/- .65	0.99 +/- .38	14.5 +/- .52	3.4
#######	5.1 +/- .25	0.37 +/- .04	10.7 +/- .71	3.06 +/- .00
#######	5.4 +/- .34	0.75 +/- .05	15.4 +/- 3.8	
2/3/2003	4.9 +/- .03	0.33 +/- .01	11.1 +/- .72	
Mean	5.22	0.62	12.93	3.23
SD	0.65	0.25	2.37	0.24
Interassay	12.5%	40.3%	18.3%	7.4%

Current assay

Sample	Patient	ng/ml	SD	Intraassay
26	55	15.75	0.92	6%
14	59	3.73	0.35	10%
18	60	4.11	0.21	5%
28	68	3.67	0.02	1%
20	71	5.17	1.08	21%
35	75	3.05	0.18	6%
5	95	2.27	0.09	4%
24	97	4.09	0.28	7%
16	99	5.80	0.29	5%
15	101	5.69	0.65	11%
9	106	5.52	0.17	3%
4	107	3.72	0.04	1%
6	112	6.50	0.13	2%
11	458	3.17	0.09	3%
36	474	3.51	0.14	4%
7	478	5.10	0.34	7%
29	488	5.31	0.07	1%
13	586	2.15	0.20	9%
2	597	3.31	0.07	2%
10	636	5.08	0.49	10%
34	637	4.03	0.27	7%
19	667	4.91	0.41	8%
1	668	4.50	0.18	4%
33	679	2.01	0.14	7%
22	681	8.09	2.00	25%
8	685	5.57	0.10	2%
25	686	13.18	0.59	4%
27	691	3.81	0.00	0%
21	701	5.38	1.11	21%
3	708	3.44	0.00	0%
31	746	3.21	0.35	11%
23	751	6.09	0.28	5%
17	756	7.08	0.24	3%
12	757	4.50	0.18	4%
32	764	2.47	0.15	6%
30	765	3.70	0.02	1%
	Level I	0.50	0.06	12%
	Level II	5.98	0.50	8%

Number of values	36
Minimum	2.006
25% Percentile	3.473
Median	4.302
75% Percentile	5.543
Maximum	15.75
Mean	4.962
Std. Deviation	2.734
Std. Error	0.4557
Lower 95% CI	4.037
Upper 95% CI	5.887

Testosterone EIA 2/5/03



(0.3 - 0.7)
(3 - 7)

Interassay samples

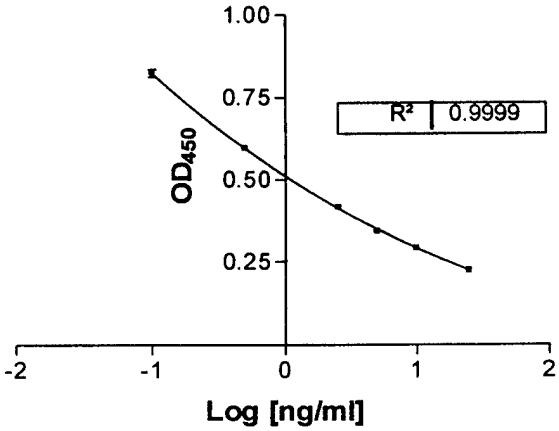
	12/20 #4	LMS	KN	778
#######	5.6 +/- .55	0.68 +/- .09		
#######	4.2 +/- .45	0.61 +/- .09		
#######	6.1 +/- .65	0.99 +/- .38	14.5 +/- .52	3.4
#######	5.1 +/- .25	0.37 +/- .04	10.7 +/- .71	3.06 +/- .00
#######	5.4 +/- .34	0.75 +/- .05	15.4 +/- 3.8	
2/3/2003	4.9 +/- .03	0.33 +/- .01	11.1 +/- .72	
2/5/2003	3.6 +/- .08	0.38 +/- .04	9.1 +/- .89	
Mean	4.99	0.59	12.16	3.23
SD	0.84	0.24	2.67	0.24

Current assay

Sample	Patient	ng/ml	SD	Intraassay
27	13	2.44	0.09	4%
1	43	14.12	2.33	17%
11	47	4.16	0.16	4%
26	50	11.32	0.84	7%
24	54	3.48	0.16	5%
20	56	8.02	0.84	10%
4	61	5.26	0.04	1%
7	64	5.09	0.53	10%
15	65	5.24	0.93	18%
8	74	4.73	0.38	8%
12	78	7.83	0.41	5%
14	79	2.80	0.24	9%
6	103	6.09	0.10	2%
3	452	4.47	0.21	5%
33	466	5.36	0.09	2%
25	497	13.28	7.98	60%
9	500	2.96	0.11	4%
5	502	5.71	0.33	6%
28	505	6.81	0.17	3%
10	538	4.75	0.64	14%
18	544	5.18	1.69	33%
29	557	2.18	0.18	8%
36	588	6.09	0.30	5%
13	616	12.25	0.23	2%
35	651	6.93	0.35	5%
19	705	2.63	0.57	22%
31	726	3.67	0.06	2%
30	729	2.66	0.27	10%
34	734	6.69	0.11	2%
32	738	3.22	0.41	13%
22	767	6.01	1.71	28%
23	772	3.90	0.33	8%
2	781	3.50	0.13	4%
16	789	4.45	0.38	9%
17	791	2.10	0.81	39%
21	794	2.33	0.03	1%
Level I		0.32	0.01	4%
Level II		6.09	0.10	2%

Number of values	36
Minimum	2.103
25% Percentile	3.349
Median	4.921
75% Percentile	6.387
Maximum	14.12
Mean	5.491
Std. Deviation	3.066
Std. Error	0.5109
Lower 95% CI	4.454
Upper 95% CI	6.529

Testosterone EIA 2/14/03



(0.3 - 0.7)

(3 - 7)

Interassay samples

	12/20 #4	LMS	KN	797	797
#######	5.6 +/- .55	0.68 +/- .09			
#######	4.2 +/- .45	0.61 +/- .09			
#######	6.1 +/- .65	0.99 +/- .38	14.5 +/- .52		
#######	5.1 +/- .25	0.37 +/- .04	10.7 +/- .71		
#######	5.4 +/- .34	0.75 +/- .05	15.4 +/- 3.8		
2/3/2003	4.9 +/- .03	0.33 +/- .01	11.1 +/- .72		
2/5/2003	3.6 +/- .08	0.38 +/- .04	9.1 +/- .89		
#######		0.35 +/- 0.07	8.7 +/- 0.5	6.8 +/- 0.4	Current assay
Mean	4.99	0.56	11.58	6.80	
SD	0.84	0.24	2.78		
Interassay	16.8%	43.0%	24.0%		

all testosterone results

Sorted by patient number

Patient	ng/ml	SD	Intraassay	Assay date
1	3.41	0.36	10%	1/29/2003
2	4.85	0.40	8%	1/29/2003
5	5.15	0.07	1%	1/29/2003
6	5.91	0.62	11%	1/27/2003
8	6.65	0.15	2%	1/29/2003
9	6.23	0.52	8%	1/29/2003
11	3.77	0.24	6%	1/29/2003
12	3.03	0.04	1%	1/29/2003
13	2.44	0.09	4%	2/14/2003
17	4.32	0.36	8%	1/27/2003
18	2.48	0.07	3%	1/29/2003
19	5.10	0.22	4%	1/27/2003
20	2.32	0.07	3%	1/27/2003
21	7.21	0.64	9%	1/27/2003
22	4.16	0.07	2%	1/27/2003
24	2.90	0.26	9%	1/29/2003
25	3.86	0.43	11%	1/27/2003
26	5.15	0.41	8%	1/27/2003
39	9.81	0.72	7%	1/27/2003
40	3.37	0.27	8%	1/27/2003
43	14.12	2.33	17%	2/14/2003
45	2.95	0.03	1%	1/31/2003
46	3.30	0.32	10%	1/29/2003
47	4.16	0.16	4%	2/14/2003
48	5.86	0.25	4%	1/27/2003
49	2.67	0.02	1%	1/29/2003
50	11.32	0.84	7%	2/14/2003
53	2.58	0.05	2%	1/31/2003
54	3.48	0.16	5%	2/14/2003
55	15.75	0.92	6%	2/5/2003
56	8.02	0.84	10%	2/14/2003
57	6.34	0.45	7%	1/31/2003
58	5.68	0.37	6%	2/3/2003
59	3.73	0.35	10%	2/5/2003
60	4.11	0.21	5%	2/5/2003
61	5.26	0.04	1%	2/14/2003
64	5.09	0.53	10%	2/14/2003
65	5.24	0.93	18%	2/14/2003
67	4.78	0.60	13%	2/3/2003
68	3.67	0.02	1%	2/5/2003
71	5.17	1.08	21%	2/5/2003
74	4.73	0.38	8%	2/14/2003
75	3.05	0.18	6%	2/5/2003
76	4.91	0.25	5%	2/3/2003
78	7.83	0.41	5%	2/14/2003
79	2.80	0.24	9%	2/14/2003
93	3.78	0.07	2%	1/31/2003
95	2.27	0.09	4%	2/5/2003
96	4.80	0.00	0%	1/31/2003
97	4.09	0.28	7%	2/5/2003

Sorted by intraassay variation

Patient	ng/ml	SD	Intraassay	Assay date	
549	1.90	2.69	141%	2/3/2003	
497	13.28	7.98	60%	2/14/2003	
791	2.10	0.81	39%	2/14/2003	
544	5.18	1.69	33%	2/14/2003	
767	6.01	1.71	28%	2/14/2003	
653	6.78	1.76	26%	1/31/2003	
681	8.09	2.00	25%	2/5/2003	
566	4.41	1.07	24%	1/29/2003	
705	2.63	0.57	22%	2/14/2003	
71	5.17	1.08	21%	2/5/2003	
701	5.38	1.11	21%	2/5/2003	
567	3.02	0.62	20%	2/3/2003	
741	6.62	1.29	20%	1/27/2003	
724	3.99	0.72	18%	2/3/2003	
65	5.24	0.93	18%	2/14/2003	>15%
503	2.90	0.50	17%	1/29/2003	17
43	14.12	2.33	17%	2/14/2003	8%
631	4.40	0.63	14%	2/3/2003	
594	4.17	0.60	14%	2/3/2003	
647	6.86	0.96	14%	2/3/2003	
627	5.78	0.78	14%	1/27/2003	
538	4.75	0.64	14%	2/14/2003	
574	3.69	0.48	13%	2/3/2003	
738	3.22	0.41	13%	2/14/2003	
67	4.78	0.60	13%	2/3/2003	
655	4.20	0.52	12%	1/27/2003	
675	4.08	0.51	12%	2/3/2003	
542	3.71	0.46	12%	1/27/2003	
453	5.26	0.64	12%	1/27/2003	
499	4.64	0.55	12%	2/3/2003	
443	3.47	0.41	12%	1/29/2003	
101	5.69	0.65	11%	2/5/2003	
x	5.83	0.66	11%	1/31/2003	
784	2.32	0.26	11%	1/29/2003	
25	3.86	0.43	11%	1/27/2003	
498	10.64	1.16	11%	1/31/2003	
746	3.21	0.35	11%	2/5/2003	
445	2.46	0.27	11%	1/29/2003	11 - 15%
673	4.85	0.52	11%	2/3/2003	23
6	5.91	0.62	11%	1/27/2003	11%
56	8.02	0.84	10%	2/14/2003	
1	3.41	0.36	10%	1/29/2003	
752	5.76	0.60	10%	1/27/2003	
64	5.09	0.53	10%	2/14/2003	
729	2.66	0.27	10%	2/14/2003	
774	3.65	0.36	10%	1/27/2003	
622	3.31	0.33	10%	1/31/2003	
595	5.14	0.51	10%	1/31/2003	
46	3.30	0.32	10%	1/29/2003	
636	5.08	0.49	10%	2/5/2003	

99	5.80	0.29	5%	2/5/2003
101	5.69	0.65	11%	2/5/2003
103	6.09	0.10	2%	2/14/2003
104	3.54	0.19	5%	2/3/2003
106	5.52	0.17	3%	2/5/2003
107	3.72	0.04	1%	2/5/2003
109	3.72	0.23	6%	1/31/2003
111	7.43	0.30	4%	1/31/2003
112	6.50	0.13	2%	2/5/2003
442	5.37	0.23	4%	1/27/2003
443	3.47	0.41	12%	1/29/2003
445	2.46	0.27	11%	1/29/2003
446	3.36	0.25	7%	1/29/2003
447	6.50	0.15	2%	1/29/2003
449	1.61	0.02	1%	1/29/2003
450	11.76	1.06	9%	1/29/2003
452	4.47	0.21	5%	2/14/2003
453	5.26	0.64	12%	1/27/2003
454	16.96	1.50	9%	1/27/2003
456	5.00	0.00	0%	2/3/2003
457	3.74	0.05	1%	1/29/2003
458	3.17	0.09	3%	2/5/2003
466	5.36	0.09	2%	2/14/2003
474	3.51	0.14	4%	2/5/2003
478	5.10	0.34	7%	2/5/2003
481	7.97	0.09	1%	1/31/2003
483	7.80	0.05	1%	1/31/2003
488	5.31	0.07	1%	2/5/2003
493	6.13	0.00	0%	1/31/2003
497	13.28	7.98	60%	2/14/2003
498	10.64	1.16	11%	1/31/2003
499	4.64	0.55	12%	2/3/2003
500	2.96	0.11	4%	2/14/2003
501	3.10	0.20	7%	1/29/2003
502	5.71	0.33	6%	2/14/2003
503	2.90	0.50	17%	1/29/2003
505	6.81	0.17	3%	2/14/2003
506	2.81	0.02	1%	2/3/2003
507	5.06	0.24	5%	1/31/2003
509	12.09	0.71	6%	2/3/2003
514	7.02	0.37	5%	2/3/2003
516	2.53	0.06	2%	2/3/2003
526	3.82	0.02	1%	1/29/2003
527	7.54	0.48	6%	1/27/2003
531	3.15	0.11	4%	2/3/2003
538	4.75	0.64	14%	2/14/2003
539	4.62	0.25	5%	1/29/2003
542	3.71	0.46	12%	1/27/2003
544	5.18	1.69	33%	2/14/2003
545	8.49	0.22	3%	1/27/2003
546	4.34	0.04	1%	1/31/2003
546	4.36	0.37	8%	1/31/2003

564	7.23	0.70	10%	1/29/2003
704	8.26	0.79	10%	2/3/2003
743	7.37	0.70	10%	1/27/2003
59	3.73	0.35	10%	2/5/2003
775	4.29	0.41	10%	1/27/2003
589	5.86	0.54	9%	1/27/2003
586	2.15	0.20	9%	2/5/2003
450	11.76	1.06	9%	1/29/2003
21	7.21	0.64	9%	1/27/2003
24	2.90	0.26	9%	1/29/2003
454	16.96	1.50	9%	1/27/2003
79	2.80	0.24	9%	2/14/2003
789	4.45	0.38	9%	2/14/2003
652	5.25	0.45	9%	1/29/2003
546	4.36	0.37	8%	1/31/2003
772	3.90	0.33	8%	2/14/2003
667	4.91	0.41	8%	2/5/2003
557	2.18	0.18	8%	2/14/2003
9	6.23	0.52	8%	1/29/2003
17	4.32	0.36	8%	1/27/2003
2	4.85	0.40	8%	1/29/2003
753	7.31	0.60	8%	1/27/2003
40	3.37	0.27	8%	1/27/2003
74	4.73	0.38	8%	2/14/2003
26	5.15	0.41	8%	1/27/2003
50	11.32	0.84	7%	2/14/2003
446	3.36	0.25	7%	1/29/2003
39	9.81	0.72	7%	1/27/2003
760	9.10	0.66	7%	1/27/2003
57	6.34	0.45	7%	1/31/2003
773	8.00	0.57	7%	1/27/2003
679	2.01	0.14	7%	2/5/2003
97	4.09	0.28	7%	2/5/2003
637	4.03	0.27	7%	2/5/2003
676	9.40	0.63	7%	1/31/2003
478	5.10	0.34	7%	2/5/2003
501	3.10	0.20	7%	1/29/2003
780	8.97	0.59	7%	1/27/2003
58	5.68	0.37	6%	2/3/2003
797	8.04	0.52	6%	1/27/2003
527	7.54	0.48	6%	1/27/2003
11	3.77	0.24	6%	1/29/2003
109	3.72	0.23	6%	1/31/2003
643	4.19	0.26	6%	2/3/2003
764	2.47	0.15	6%	2/5/2003
786	15.10	0.93	6%	2/3/2003
666	6.29	0.38	6%	1/31/2003
779	4.47	0.27	6%	1/27/2003
625	9.45	0.56	6%	1/27/2003
75	3.05	0.18	6%	2/5/2003
509	12.09	0.71	6%	2/3/2003
55	15.75	0.92	6%	2/5/2003

547	2.54	0.13	5%	1/29/2003
549	1.90	2.69	141%	2/3/2003
557	2.18	0.18	8%	2/14/2003
564	7.23	0.70	10%	1/29/2003
566	4.41	1.07	24%	1/29/2003
567	3.02	0.62	20%	2/3/2003
571	9.40	0.06	1%	1/31/2003
571	9.64	0.06	1%	1/31/2003
572	5.21	0.03	1%	2/3/2003
573	3.61	0.04	1%	2/3/2003
574	3.69	0.48	13%	2/3/2003
575	7.08	0.28	4%	1/31/2003
575	7.46	0.26	3%	1/31/2003
577	3.38	0.10	3%	1/29/2003
578	4.61	0.16	4%	1/31/2003
580	2.62	0.09	4%	2/3/2003
586	2.15	0.20	9%	2/5/2003
588	6.09	0.30	5%	2/14/2003
589	5.86	0.54	9%	1/27/2003
594	4.17	0.60	14%	2/3/2003
595	5.14	0.51	10%	1/31/2003
597	3.31	0.07	2%	2/5/2003
598	7.26	0.24	3%	2/3/2003
600	10.11	0.36	4%	2/3/2003
606	6.20	0.03	1%	1/31/2003
613	3.68	0.04	1%	2/3/2003
616	12.25	0.23	2%	2/14/2003
622	3.31	0.33	10%	1/31/2003
625	9.45	0.56	6%	1/27/2003
627	5.78	0.78	14%	1/27/2003
631	4.40	0.63	14%	2/3/2003
635	4.13	0.00	0%	1/31/2003
635	5.90	0.32	5%	1/31/2003
636	5.08	0.49	10%	2/5/2003
637	4.03	0.27	7%	2/5/2003
639	15.32	0.33	2%	1/31/2003
641	4.10	0.16	4%	1/31/2003
643	4.19	0.26	6%	2/3/2003
647	6.86	0.96	14%	2/3/2003
649	1.89	0.03	2%	1/31/2003
651	6.93	0.35	5%	2/14/2003
652	5.25	0.45	9%	1/29/2003
653	6.78	1.76	26%	1/31/2003
655	4.20	0.52	12%	1/27/2003
663	6.70	0.09	1%	2/3/2003
665	7.54	0.15	2%	2/3/2003
666	6.29	0.38	6%	1/31/2003
667	4.91	0.41	8%	2/5/2003
668	4.50	0.18	4%	2/5/2003
673	4.85	0.52	11%	2/3/2003
675	4.08	0.51	12%	2/3/2003
676	9.40	0.63	7%	1/31/2003

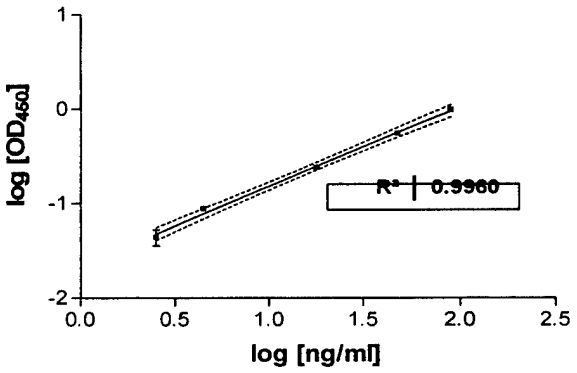
502	5.71	0.33	6%	2/14/2003
104	3.54	0.19	5%	2/3/2003
539	4.62	0.25	5%	1/29/2003
635	5.90	0.32	5%	1/31/2003
742	4.41	0.24	5%	1/29/2003
514	7.02	0.37	5%	2/3/2003
771	8.07	0.43	5%	1/31/2003
78	7.83	0.41	5%	2/14/2003
60	4.11	0.21	5%	2/5/2003
547	2.54	0.13	5%	1/29/2003
651	6.93	0.35	5%	2/14/2003
99	5.80	0.29	5%	2/5/2003
76	4.91	0.25	5%	2/3/2003
588	6.09	0.30	5%	2/14/2003
452	4.47	0.21	5%	2/14/2003
507	5.06	0.24	5%	1/31/2003
751	6.09	0.28	5%	2/5/2003
54	3.48	0.16	5%	2/14/2003
686	13.18	0.59	4%	2/5/2003
48	5.86	0.25	4%	1/27/2003
442	5.37	0.23	4%	1/27/2003
19	5.10	0.22	4%	1/27/2003
739	9.38	0.39	4%	2/3/2003
668	4.50	0.18	4%	2/5/2003
757	4.50	0.18	4%	2/5/2003
95	2.27	0.09	4%	2/5/2003
111	7.43	0.30	4%	1/31/2003
749	6.64	0.26	4%	2/3/2003
575	7.08	0.28	4%	1/31/2003
641	4.10	0.16	4%	1/31/2003
47	4.16	0.16	4%	2/14/2003
474	3.51	0.14	4%	2/5/2003
781	3.50	0.13	4%	2/14/2003
500	2.96	0.11	4%	2/14/2003
531	3.15	0.11	4%	2/3/2003
580	2.62	0.09	4%	2/3/2003
600	10.11	0.36	4%	2/3/2003
13	2.44	0.09	4%	2/14/2003
578	4.61	0.16	4%	1/31/2003
694	4.33	0.15	3%	1/31/2003
818	3.24	0.11	3%	1/27/2003
575	7.46	0.26	3%	1/31/2003
756	7.08	0.24	3%	2/5/2003
598	7.26	0.24	3%	2/3/2003
106	5.52	0.17	3%	2/5/2003
577	3.38	0.10	3%	1/29/2003
801	1.06	0.03	3%	1/29/2003
18	2.48	0.07	3%	1/29/2003
20	2.32	0.07	3%	1/27/2003
458	3.17	0.09	3%	2/5/2003
737	4.33	0.11	3%	1/29/2003
545	8.49	0.22	3%	1/27/2003

679	2.01	0.14	7%	2/5/2003
680	3.98	0.10	2%	1/31/2003
681	8.09	2.00	25%	2/5/2003
685	5.57	0.10	2%	2/5/2003
686	13.18	0.59	4%	2/5/2003
691	3.81	0.00	0%	2/5/2003
694	4.33	0.15	3%	1/31/2003
701	5.38	1.11	21%	2/5/2003
702	2.43	0.06	2%	2/3/2003
703	4.81	0.02	1%	1/31/2003
704	8.26	0.79	10%	2/3/2003
705	2.63	0.57	22%	2/14/2003
708	3.44	0.00	0%	2/5/2003
717	6.47	0.00	0%	1/31/2003
724	3.99	0.72	18%	2/3/2003
726	3.67	0.06	2%	2/14/2003
729	2.66	0.27	10%	2/14/2003
730	4.40	0.03	1%	2/3/2003
734	6.69	0.11	2%	2/14/2003
737	4.33	0.11	3%	1/29/2003
738	3.22	0.41	13%	2/14/2003
739	9.38	0.39	4%	2/3/2003
741	6.62	1.29	20%	1/27/2003
742	4.41	0.24	5%	1/29/2003
743	7.37	0.70	10%	1/27/2003
746	3.21	0.35	11%	2/5/2003
749	6.64	0.26	4%	2/3/2003
751	6.09	0.28	5%	2/5/2003
752	5.76	0.60	10%	1/27/2003
753	7.31	0.60	8%	1/27/2003
755	3.64	0.00	0%	2/3/2003
756	7.08	0.24	3%	2/5/2003
757	4.50	0.18	4%	2/5/2003
760	9.10	0.66	7%	1/27/2003
764	2.47	0.15	6%	2/5/2003
765	3.70	0.02	1%	2/5/2003
767	6.01	1.71	28%	2/14/2003
771	8.07	0.43	5%	1/31/2003
772	3.90	0.33	8%	2/14/2003
773	8.00	0.57	7%	1/27/2003
774	3.65	0.36	10%	1/27/2003
775	4.29	0.41	10%	1/27/2003
777	4.02	0.05	1%	1/29/2003
778	3.40	0.00	0%	1/27/2003
778	3.06	0.00	0%	1/29/2003
779	4.47	0.27	6%	1/27/2003
780	8.97	0.59	7%	1/27/2003
781	3.50	0.13	4%	2/14/2003
784	2.32	0.26	11%	1/29/2003
785	5.10	0.09	2%	1/27/2003
786	15.10	0.93	6%	2/3/2003
787	8.07	0.16	2%	1/27/2003
505	6.81	0.17	3%	2/14/2003
680	3.98	0.10	2%	1/31/2003
516	2.53	0.06	2%	2/3/2003
702	2.43	0.06	2%	2/3/2003
8	6.65	0.15	2%	1/29/2003
447	6.50	0.15	2%	1/29/2003
597	3.31	0.07	2%	2/5/2003
639	15.32	0.33	2%	1/31/2003
665	7.54	0.15	2%	2/3/2003
112	6.50	0.13	2%	2/5/2003
787	8.07	0.16	2%	1/27/2003
93	3.78	0.07	2%	1/31/2003
616	12.25	0.23	2%	2/14/2003
685	5.57	0.10	2%	2/5/2003
785	5.10	0.09	2%	1/27/2003
53	2.58	0.05	2%	1/31/2003
22	4.16	0.07	2%	1/27/2003
799	2.71	0.05	2%	1/29/2003
649	1.89	0.03	2%	1/31/2003
734	6.69	0.11	2%	2/14/2003
103	6.09	0.10	2%	2/14/2003
466	5.36	0.09	2%	2/14/2003
726	3.67	0.06	2%	2/14/2003
5	5.15	0.07	1%	1/29/2003
794	2.33	0.03	1%	2/14/2003
663	6.70	0.09	1%	2/3/2003
777	4.02	0.05	1%	1/29/2003
796	3.91	0.05	1%	1/29/2003
457	3.74	0.05	1%	1/29/2003
488	5.31	0.07	1%	2/5/2003
613	3.68	0.04	1%	2/3/2003
573	3.61	0.04	1%	2/3/2003
12	3.03	0.04	1%	1/29/2003
481	7.97	0.09	1%	1/31/2003
798	2.57	0.03	1%	1/29/2003
107	3.72	0.04	1%	2/5/2003
449	1.61	0.02	1%	1/29/2003
546	4.34	0.04	1%	1/31/2003
45	2.95	0.03	1%	1/31/2003
61	5.26	0.04	1%	2/14/2003
526	3.82	0.02	1%	1/29/2003
572	5.21	0.03	1%	2/3/2003
730	4.40	0.03	1%	2/3/2003
571	9.64	0.06	1%	1/31/2003
571	9.40	0.06	1%	1/31/2003
506	2.81	0.02	1%	2/3/2003
483	7.80	0.05	1%	1/31/2003
49	2.67	0.02	1%	1/29/2003
765	3.70	0.02	1%	2/5/2003
68	3.67	0.02	1%	2/5/2003
606	6.20	0.03	1%	1/31/2003
703	4.81	0.02	1%	1/31/2003

789	4.45	0.38	9%	2/14/2003	96	4.80	0.00	0%	1/31/2003	
791	2.10	0.81	39%	2/14/2003	456	5.00	0.00	0%	2/3/2003	
794	2.33	0.03	1%	2/14/2003	493	6.13	0.00	0%	1/31/2003	
796	3.91	0.05	1%	1/29/2003	635	4.13	0.00	0%	1/31/2003	
797	8.04	0.52	6%	1/27/2003	691	3.81	0.00	0%	2/5/2003	
798	2.57	0.03	1%	1/29/2003	708	3.44	0.00	0%	2/5/2003	
799	2.71	0.05	2%	1/29/2003	717	6.47	0.00	0%	1/31/2003	
801	1.06	0.03	3%	1/29/2003	755	3.64	0.00	0%	2/3/2003	**1 - 10%**
818	3.24	0.11	3%	1/27/2003	778	3.40	0.00	0%	1/27/2003	**176**
x	5.83	0.66	11%	1/31/2003	778	3.06	0.00	0%	1/29/2003	**81%**

Sample	conditions	Previous Assay values				
		var. dates	% of mean	########	% of mean	ng/ml
Expo 136	stored 4c O/N	3667	81			2034
Expo 136	thawed 10:15 am					2003
Expo 136	thawed 11:15 am					2030
GU 628	thawed 11:15 am	4183	128	3517	101	2695
GU 32	thawed 11:15 am	3470	106	3290	95	2766
GU 459	thawed 11:15 am	2934	125	3870	112	3020
12/20 #4	thawed 11:15 am			3626	105	2681
LMS	thawed 11:15 am			3609	104	2940
GU 596	thawed 11:15 am	2200	94	2896	83.5	2147
GU 596	stored 4c 30days, RT O/N					962
Expo 128	stored 4c 30days	6120		4227		3473
	Mean of samples 5-10			3468		2708

IGFBP3 ELISA
1/10/03



Controls	expected	actual	SD
Level I	4.5 +/- 1.5	6.2	1.1
Level II	18 +/- 5.5	20.4	1.8

Number of va	9	
Minimum	2003	
25% Percenti	2034	
Median	2681	
75% Percenti	2695	
Maximum	3020	
Mean	2480	(includes exceptional samples)
Std. Deviatior	420.1	
Std. Error	140	
Lower 95% C	2157	
Upper 95% C	2803	

1/10/2003

SD	% of mean	
50	77	(mean inc. 136)
94		
82		
86	99.5	
265	102	
40	111.5	
92	99	
33	109	
210	79	
217		
234		

Sample		1/10/2003		12/10/2002	
		ng/ml	SD	ng/ml	SD
Level I (0.5 +/- 0.2)		0.48	0.06	0.60	0.05
Level II (5 +/- 2)		5.07	0.14	4.15	0.56
Expo 136	stored 4c O/N	3.96	0.36		
Expo 136	thawed 10:15 am	4.17	0.29		
Expo 136	thawed 11:15 am	3.93	0.02		
GU 628	thawed 11:15 am	1.37	0.03	1.30	0.34
GU 32	thawed 11:15 am	5.39	0.19	5.98	0.83
GU 459	thawed 11:15 am	12.20	1.44	14.53	2.36
12/20 #4	thawed 11:15 am	4.19	0.45	5.63	0.55
LMS	thawed 11:15 am	0.61	0.09	0.68	0.09
GU 596	thawed 11:15 am	5.64	0.82		
GU 596	stored 4c 30d RT o/n	6.02	1.11		
Expo 128	stored 4c 30days	2.64	0.13	2.53 (fresh)	0.61
		R^2 0.9997		R^2 0.9977	

1/10/03 Testosterone EIA